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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,770	12/29/2000	Kuber T. Sampath	00960-520PRO	7664

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/581,770	SAMPATH ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/10/1005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,22-24,31 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22-24,31 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/10/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Request filed on 01/10/2005 for Continued Examination (RCE) under 37 CFR 1.114 of Application 09/581,770 is granted. An action on the RCE follows.

The amendment filed on 11/01/2004 has been entered in full. Claims 26 and 34 have been canceled. Claims 20 and 31 have been amended. Claim 39 has been added. Claims 20, 22-24, 31, and 39 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

Applicants' cancellation of claims 26 and 34 has made all the rejections and objections related to these claims set forth in the previous office actions moot.

The rejection of claims 20, 22-24, 26, 31, and 34 under 35 U.S.C. § 112, 1st paragraph, as set forth at pages 6-8 in the previous office action (Paper No. 1203, mailed on December 17, 2003), has been withdrawn in view of canceled claims, amended claims, the information disclosure statement submitted on 02/10/2005, and Applicants' argument.

Claim Rejections under Nonstatutory Obviousness-Type Double Patenting

The rejection of claims 20, 22-24, and 31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1, as set forth at pages 4-5 in the previous office action mailed on December 17, 2003, is maintained. New claim 39 is also rejected on the same basis.

Claims 20, 22-24, 31, and 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. U.S. Patent No. 6,498,142 B1 teaches a method of treatment for a mammal at risk of chronic renal failure, which comprises administering to said mammal a therapeutically effective amount of a morphogen (e.g., OP-1). Treatment of cells with a morphogen (e.g., OP-1) necessarily causes specific binding of a morphogen to its transmembrane receptor and phosphorylation of a Smad protein, and induces translocation of Smad complex into the cell's nucleus, leading to expression of a phenotype-specific gene, since activation of an intracellular pathway that induces intracellular formation of a Smad complex is inherent to the morphogen (e.g., OP-1). In the instant application, the claims are drawn to a method for restoring cellular phenotype in a subject's cell affected by disease, damage or age, comprising administering to the subject an effective amount of a morphogen.

Therefore, the patented claims are related to the instant claims as species to genus. A patented species renders its genus obvious and thus anticipates the genus. That is, claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1 falls entirely within the scope of instant claims 20, 22-24, 31, and 39, or in other words, claims 20, 22-24, 31, and 39 of the instant application are anticipated by claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1. Specifically, treatment of chronic renal failure or a renal condition recited in claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1 is encompassed by the instant claims 20, 22-24, 26, 31, and 34 that recite restoring cellular phenotype in a subject's cell (a lung cell, a heart cell, a blood vessel, a stomach cell, a muscle cell, a renal cell or an intestinal cell) affected by disease, damage or age.

Beginning at the bottom of page 5 of Applicants' response filed on 11/01/2004, Applicants argue that anticipation is not a proper basis for an obviousness type double patenting pursuant to MPEP 804 (II). Citing MPEP, Applicants argue that the rejection is based on the alleged dominance of the claims from the subject application over the claims of the '142 patent, such a rejection is not proper. This is not persuasive because the presence of domination does not preclude double patenting (MPEP 804, II, top of right column of page 804). In the instant case, claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1 falls entirely within the scope of instant claims 20, 22-24, 31, and 39, or in other words, claims 20, 22-

24, 31, and 39 are anticipated by claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1. Thus, the rejection is proper and maintained.

Claim Rejections under 35 USC § 102 (b)

(i). Claims 20, 22-24, 31, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen et al. (WO 92/15323, September 17, 1992).

Cohen et al. teach various morphogens, including human and mouse OP-1, OP-2 (page 11, line 13). Cohen et al. also teach that morphogens can be used to repair damaged tissue, such as damaged lung tissue resulting from emphysema, cirrhotic kidney or liver tissue, damaged heart or blood vessel tissue, as may result from cardiomyopathies and/or atherothrombotic or cardioembolic strokes, damaged stomach tissue resulting from ulceric perforations (see, e.g., bottom of page 6 to top of page 7; claims 15-30). Cohen et al. further teach that morphogens may be used to support the growth and maintenance of differentiated cells, inducing existing differentiated cells to continue expressing their phenotype (page 9, lines 8-12). Treatment of cells with a morphogen (e.g., OP-1) necessarily causes specific binding of a morphogen to its transmembrane receptor and phosphorylation of a Smad protein, and induces translocation of Smad complex into the cell's nucleus, leading to expression of a phenotype-specific gene. Thus, the reference of Cohen et al. meets the limitations of claims 20, 22-24, 31, and 39.

(ii). The rejection of claims 20, 22-24, and 31 under 35 U.S.C. § 102 (b) as being anticipated by Kuberasampath et al., as set forth at pages 11-12 in the previous office action mailed on December 17, is maintained. New claim 39 is also rejected on the same basis.

Claims 20, 22-24, 31, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuberasampath et al. (WO 94/06449, March 31, 1994).

Kuberasampath et al. teach morphogen-induced liver regeneration. Specifically, Kuberasampath et al. teach therapeutic treatment methods for maintaining liver function in a mammal, including regenerating lost or damaged hepatic tissue, enhancing viability and integration of hepatic tissue and correcting liver function deficiencies (including enhancing diminished liver function due to tissue injury or disease)(see, e.g., Abstract). The methods comprise providing a therapeutically effective morphogen concentration to the hepatic cells that are obviously soft tissue cells (see, e.g., claims). Kuberasampath et al. also teach treatment of transplant tissues, e.g., liver, lung, kidney, pancrease, heart, etc., to provide a cytoprotective effect to the tissue (line 17-23 of page 18). Kuberasampath et al. further teach the expression of OP-1 in kidney-related tissue, brain, heart, lung tissues (lines 24-27 of page 91). Kuberasampath et al. further teach specific morphogens, including OP-1 and OP-2 (see, e.g., claims 41-44). It is noted that activation of an intracellular pathway that induces intracellular formation of a Smad complex is inherent to the morphogen (e.g., OP-1). Treatment of cells with

a morphogen (e.g., OP-1) necessarily causes specific binding of a morphogen to its transmembrane receptor and phosphorylation of a Smad protein, and induces translocation of Smad complex into the cell's nucleus, leading to expression of a phenotype-specific gene. Thus, the reference of Kuberasampath et al. meets the limitations of claims 20, 22-24, 31, and 39.

Beginning at the bottom of page 11 of Applicants' response, Applicants argue that the Examiner concedes that applicant's claims amendment did overcome the hepatocyte rejection previously raised, and proceeds to set forth a new ground for the rejection. This is not found to be persuasive. The previous office action (page 7 of Paper No. 05242004) states the following:

"Applicants argue that the amended claims recite specific cell types, i.e., lung cells, heart cells, blood vessel cells, renal cells, stomach cells and intestinal cells, but do not recite hepatocytes. This has been fully considered, but is not deemed to be persuasive because Kuberasampath et al. not only teach the use of morphogens to maintain liver function in a mammal, but also teach treatment of transplant tissues, e.g., liver, lung, kidney, pancrease, heart, etc., to provide a cytoprotective effect to the tissue (line 17-23 of page 18). Kuberasampath et al. further teach the expression of OP-1 in kidney-related tissue, brain, heart, lung tissues (lines 24-27 of page 91). Thus, the reference of Kuberasampath et al. still meets the limitations of the amended claims".

It is noted that the Examiner made the above comments in response to Applicants' argument and amendment. If Applicants consider it as a new ground of rejection, it is necessitated by Applicants' amendment and the office action is properly made final. See MPEP §706.07 (a).

At the middle of page 12, Applicants argue that claims 20 and 31, from which all other claims dpend, recite the use of a morphogen to treat a cell affected by disease, damage, or age. This feature of the claimed invention is not anticipated by the cited reference. Applicants argue that if an organ were to be transplanted from one subject to another, one skilled in the art would not select a donor organ that is affected by disease, damage, or age. Therefore, the cited reference of Kuberasampath et al. does not teach the use of morphogens to treat diseased, damaged, or aged-afflicted organs with a morphogen. This is not persuasive because Kuberasampath et al. not only teach therapeutic treatment methods for maintaining liver function in a mammal, including regenerating lost or damaged hepatic tissue, enhancing viability and integration of hepatic tissue and correcting liver function deficiencies (including enhancing diminished liver function due to tissue injury or disease), but also teach treatment of transplant tissues, e.g., liver, lung, kidney, pancrease, heart, etc., to provide a cytoprotective effect to the tissue (line 17-23 of page 18). Thus, the disclosure of Kuberasampath et al., as a whole, teaches the limitations of the claimed methods. Moreover, hepatic tissue also comprise blood vessels and regenerating lost or damaged hepatic tissue also involves regeneration of blood vessels. Kuberasampath et al. inherently

teach a method for restoring cellular type in a blood cell with a morphogen. Finally, an organ to be transplanted from one subject to another, albeit from a healthy donor, is damaged in the sense that such an organ is separated from the donor's body and loses the function of the organ before being transplanted.

Accordingly, the claims are anticipated by the cited reference and the rejection of claims 20, 22-24, 31, and 39 under 35 U.S.C. § 102 (b) is required .

Claim Objections

Claims 20, 22-24, 31, and 39 are objected to because they recite non-elected subject matter (non-elected species). Appropriate correction is required.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Examiner
April 15, 2005